REMARKS

This application has been reviewed in light of the Notice of Non-Responsive Amendment dated January 25, 2010. Claims 24-26, 29-39, 58 and 59 are pending in this application with claims 24 and 59 being the only claims in independent form. Claims 1-23 and 41-57 were previously withdrawn in a Response to Restriction and Election-of-Species Requirement electronically filed on January 14, 2009. Claims 24, 32-34 and 37 have been amended, with the subject matter from canceled claim 27 being added to independent claim 24. In addition, new claim 59 includes the subject matter from claim 24 and the features recited in dependent claims 33 and 34. Favorable reconsideration is respectfully requested.

The Notice of Non-Responsive Amendment stated that pursuant to the requirements of 37 C.F.R. § 1.121[c] the text of withdrawn claims must be included in the listing of claims. Applicant have included the text of withdrawn claims 1-23 and 40-57 in this paper and therefore submit that the Notice of Non-Responsive Amendment has been obviated.

As requested, Applicants also submit herewith the response to the Office Action dated March 31, 2009.

The Office Action objected to:

i) claim 24 for failing to define the acronym "NMDA" at its first occurrence; claim 24 has been amended to recite "N-methyl-D-aspartate" for "NMDA" as disclosed in paragraph [0005] of the published application;

ii) claim 27 for failing to define the acronym "HT" at its first occurrence; claim 27 has been amended to recite "hydrohytryptamine" for "HT" as understood by a person of ordinary skill in the art; we also note that the specification, at least at paragraph [0082] of the published application states that "[t]he term "antidepressant" as used herein includes compounds that when administered systemically in a mammal, act as 5-HT.sub.1A-receptor agonist, antagonists, and partial agonists ("5-HT.sub.1A agents") or that when tested according to standard in vivo or in vitro assays, act as 5-HT.sub.1A-receptor agonist, antagonists, and partial agonists. One of skill in the art can readily identify 5-HT.sub.1A agents by in vivo and in vitro assays. For example, 5-HT.sub.1A agents can be identified by adapting the 5-HT.sub.1A receptor binding assays described in U.S. Pat. No. 6,255,302 (issued Jul. 3, 2001) or 6,239,194 (issued May 29, 2001), which patents are hereby expressly incorporated herein by reference. Examples of 5-HT.sub.1A agents include, but are not limited to, buspirone, flesinoxan, gepirone, and ipsapirone, and pharmaceutically acceptable salts thereof and those disclosed in U.S. Pat. Nos. 6,255,302; 6,245,781 (issued Jun. 12, 2001); and 6,242,448 (issued Jun. 5, 2001). An example of a compound with 5-HT.sub.1A

receptor antagonist/partial agonist activity is pindolol.

iii) claim 27 for failing to define the acronym "NK1"; claim 27 has been amended to recite "neurokinin 1" for "NK1" as understood by a person of ordinary skill in the art; and

iv) claim 33 for failing to define the acronym "PCP"; claim 33 has been amended to recite "phencyclidine" for "PCP" as disclosed at least in paragraph [0101] of the published application.

Applicants submit that the above changes respond to the Examiner's objections. Therefore, Applicants request that the objections be withdrawn.

The Office Action rejected claims 24-27, 29-39 and 58 are rejected under U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. In particular, the Examiner stated that "it is unclear if it is the skin or the mammal that is, in fact, in need to topical administration of the instantly claimed emulsion." Applicants submit that the claim's preamble is directed to "A method of treating pain in a mammal comprising topically administering *to the skin* of a mammal" so Applicants submit that the topical administration is to the skin of a mammal. In addition, the Examiner stated that the recitation "in need thereof" lacked antecedent basis; in an effort to make the preamble more clear, Applicants have deleted this recitation. Moreover, the Examiner stated that the recitation "a therapeutically effective amount of an NMDA receptor antagonists is indefinite, as "an" is indicative of a single antagonist, but the term "antagonists" circumscribes more than one antagonist. In an effort to clarify this point, Applicants have amended claim 24 to delete the "an" and "s" at the end of the recitation "antagonist." Applicants submit, however, that this effort to clarify this point for the Examiner in no way limits the antagonist to simply one antagonist. The specification is replete with examples of different antagonists being used in combination to treat or ameliorate pain. In addition, Applicants remind the Examiner that paragraph [0041] of the published application states "[a]s used herein, a 'therapeutically effective amount' of an antidepressant or an NMDA-receptor antagonist means the amount of the antidepressant or the NMDA-receptor antagonist required in a composition of the invention to induce a local-anesthetic effect sufficient to treat or ameliorate pain in a mammal." Lastly, Applicants note for the Examiner's benefit the discussion at paragraphs [0089] to [0093] of the published application, specifically paragraph [0093] which states "[p]referably, the NMDA-receptor antagonist is a non-competitive NMDA-receptor antagonists, more preferably, ketamine, even more preferably, ketamine hydrochloride." As noted therein, the receptor antagonists may be one or more antagonists. Also, dependent

claim 35, which depends from claim 24, provides a number of examples (not just one) of NMDA receptor antagonists. In addition, based on the amendment to claim 24, Applicants submit that the use of the claim recitation "the NMDA receptor antagonist" in claims 33-35 have antecedent basis.

The Office Action also rejected claims 30 and 35 under U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. In particular, regarding claim 30, the Examiner mentioned that "or a pharmaceutically acceptable salt thereof" in line 7 of claim 30 was not clear; the claim, as the Examiner points out in the Office Action, is intended to circumscribe the use of a pharmaceutically acceptable salt of *any* one of the compounds recited in the claim. Applicants also note that the recitation "pharmaceutically acceptable salt(s)" is defined in paragraph [0047] of the published application. Regarding claim 35, the use of "or a pharmaceutically acceptable salt thereof " in line 7 of claim 35 is also intended to circumscribe the use of a pharmaceutically acceptable salt of *any* one of the compounds recited in the claim. Like claim 30, Applicants also note that the recitation "pharmaceutically acceptable salt(s)" is defined in paragraph [0047] of the published application.

The Office Action rejected claims 32 and 37 under U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as their invention. With respect to the recitation "the amount of the antidepressant" in line 1 of claims 32 and 37, these claims have been amended to more clearly recite "[an] the therapeutically effective amount of the antidepressant ...."

The Office Action rejected claims 33 and 34 under U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as their invention. The Examiner pointed out that the use of the recitation "or a pharmaceutically acceptable salt thereof" is unclear. Applicants have deleted this recitation from claims 33 and 34.

The Office Action rejected claims 24-27, 29-39 and 58 under U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,461,600 (Ford) in view of Remington's Pharmaceutical Sciences (Fifteenth Edition; 1975; p.327-339, 1452-1456). Applicants respectfully traverse this rejection.

Applicants submit that claim 24 has been amended to include the features from canceled dependent claim 27, noting that Ford in view of Remington's Pharmaceutical Sciences would not disclose the features recited in amended claim 24 including the features directed to the antidepressant being a norepinephrine reuptake inhibitor, a selective serotonin

reuptake inhibitor, a monoamine oxidase inhibitor, a serotonin and noradrenaline reuptake inhibitor, a corticotropin releasing factor antagonist, an alpha. adrenoreceptor antagonist, an neurokinin 1 receptor antagonist, a 5 hydrohytryptamine sub.1A receptor agonist, a 5 HT.sub.1A receptor antagonist, a 5 HT.sub.1A receptor partial agonist, an atypical antidepressant, or an other antidepressant or a pharmaceutically acceptable salt thereof.

In addition, Applicants have added a new claim 59 that includes claim 24 and the features recited in dependent claims 33 and 34, noting that Ford in view of Remington's Pharmaceutical Sciences would not disclose the features recited in new claim 59.

In light of the above amendments and remarks, Applicants respectfully request that the Examiner reconsider this application with a view towards allowance. The Examiner is invited to call the undersigned attorney if a telephone call could help resolve any remaining items.

Respectfully submitted,

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By: Peter G. Thurlow (Reg. No. 47,138)

JONES DAY
222 East 41st Street
New York, New York 10017
(212) 326-3694